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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/506,472
Filing Date: April 06, 2005
Appellant(s): MARSHALL ET AL.

Robert J. Patch (Reg. No. 17355)
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 4/23/2009 appealing from the Office action mailed 3/18/2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The statement of grounds of rejection to be reviewed on appel in the Appeal Brief is substantially correct.

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner:

The rejection of claims 9-13 under 35 USC § 112(2nd) has been withdrawn in view of the appellant's arguments. (Br. at 4, ¶ 3-6, ¶ 1).

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,270,479	Bergens et al	8-2001

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

Claims 9-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Bergens et al (6270479). An injection device (Figs 1A-D) comprising: a housing (Figs 1A-D) having a forward end and a rearward end; a syringe (120) having a needle (123) and containing a dose (120; Figs 1A-D) for being ejected through said needle by means of a piston (125) slideable within the syringe, said syringe being moveable within the housing to a forward position to project its needle (Figs 1b-1c) from the forward end of the housing; a spring drive operable firstly to urge the syringe to its forward position and then to press said piston to eject said dose (Figs 1A-D), said drive including: a first spring (141) acting between the housing and a plunger (126) aligned to cooperate with the piston (126) to urge the piston forwardly, and a second spring (156) acting in compression (col 12, lns 46-50, col 13 lns 2-6; Figs 1A-D) between said plunger and the syringe and in opposition to said first spring when the plunger presses said piston forwards to eject the dose (col 12, lns 7-col 13, lns 19), the second spring being weaker than the first spring but being sufficiently stiff to be in an expanded state when the syringe reaches its forward position with its needle penetrating the flesh of a patient (col

12, lns 14-17, 29-33, 47-50, and col 13, lns 1-9), whereupon the first spring, as it fully expands, will then compress the second spring to urge the plunger forward and thereby move the piston and expel a dose from the syringe (col 12, lns 14-17, 29-33, 47-50, and col 13, lns 1-9); further comprising a third, light spring (134) urging the syringe rearwardly so that its needle is retracted within the housing prior to use (Fig 1A); wherein the ejection of said dose is caused by further expansion of said first spring and is accompanied by compression of said second spring throughout the stroke of movement of said piston (col 12, lns 14-17, 29-33, 47-50, and col 13, lns 1-9); wherein during initial expansion movement of said first spring, said piston is isolated from the thrust of said first spring solely by the opposing force of the second spring (col 12, lns 14-17, 29-33, 47-50, and col 13, lns 1-9; Figs 1A-D; wherein upon initial release of 1st spring 141 the syringe moves forwards (Figs 1—1B) compressing 3rd spring 134); wherein the first spring contacts the plunger and the housing and the second spring contacts the plunger and the syringe (Figs 1a-d; col 12 and 13; wherein the scope of the term 'contacts' includes 'in association' or 'in connection' or 'in interaction').

The Examiner notes that Bergens et al explicitly discloses:

1. The damper can be arranged for energy absorption from the autopenetration movement, for which purpose the damper should yield under a pressure weaker than the force provided by the autopenetration drive but preferably be stronger than force provided by the autoreturn mechanism when present. (col 9, lns 23-28)

2. Most preferably a damper is arranged for energy absorption from the autoinjection movement, for which purpose the damper should yield under a pressure weaker than the force provided by the autoinjection drive. (col 9, lns 62-67)

3. During autoinjection, however, it is preferred that a damper is additionally or alternatively provided for the purpose of controlling injection movement speed and force in order to make the autoinjection phase usable for a broad range of forces with maintained uniform movements speeds, as described in the introduction. (col 10, lns 3-9)

4. As indicated the damper should preferably be arranged to be active during the actual injection stroke as well as during any further initial length necessary for allowing the injection head to start from a for all container types contemplated common start position for the injection phase. (col 10, lns 30-36)

5. The latter can be accomplished if the damper is connected between the autopenetration head and the autoinjection head, whereby damper movement will only take place when the injection head moves relative the penetration head, normally after completed penetration. (col 10, lns 40-46)

6. A common drive system includes a spring 141 acting as both as penetration drive and injection drive. (col 12, lns 14-16)

7. Between the syringe plunger 151 and the plunger guide 153 a compression damper spring 156 is arranged in slots, biasing the plunger guide 153 towards a rear position relative the syringe plunger 151. (col 12, lns 29-33)

8. The tapering surfaces become active for compression of the legs when the plunger guide moves forward relative the syringe plunger against the force of the damper spring, which is weaker than the drive spring 141. (col 12, lns 46-50)

9. The drive spring 141 is compressed. The container 120 is pressed to a rear needle-hidden position by return spring 134. In FIG. 1B a trigger (not shown) has been released and drive spring 141 has acted on injection head 142, which in turn has acted on plunger guide 153 to move syringe plunger 151, into contact with container barrel or fingergrip 124, thereby moving the container and carrier 130 into a needle-exposed position. At the end of this penetration movement the container and carrier have stopped together with syringe plunger 151 but the plunger guide 153 has continued its forward movement against the weaker force of damping spring 156, the relative movement between which parts has made the tapering surface 161 cause a compression of legs 143 and the injection head has landed on container plunger 126. (col 12, lns 63-col 13, lns 8).

10. Bergens et al explicitly discloses that the second spring (156) acts in direct opposition - ie dampining - to the first spring during the penetration stage after the needle has finished the penetration stage and has penetrated the skin of the patient.

11. The Examiner notes that after the conclusion of the penetration stage, the legs (143) move into expansion cavity (163) at a position that corresponds to the plunger's final position in the empty syringe (col 12, lns 50-58; Fig 1D), and this allows the needle and syringe to be retracted under the force of the 3rd return spring (134).

(10) Response to Argument

The Appellant argues that:

1. A person of ordinary skill in the art would be lost in understanding Bergens et al (Br. at 6, ¶ 3 & 4).

The Examiner notes that Bergens et al is an issued US patent and has thus met all requirements to one of ordinary skill in the art for disclosure and enablement pursuant to 35 USC 101 and 112. Secondly, the Examiner has discussed the reference in-depth on the record and finds no confusion in the operation of Bergens et al. Lastly, the possible modes of operation discussed in the Remarks by the Applicant are purely speculative in nature and ignore the disclosure and description present in Bergens et al. See MPEP 2121.01.

2. The spring 156 of Bergens et al does not act between the plunger and the syringe. (Br. at 9, ¶ 2 & 10, ¶ 3).

The Examiner notes that the appellant claims a first spring acting between the housing and a plunger, and a second spring acting between the plunger and then

syringe. The first spring (141) directly acts upon a housing and an injection head (142) (Figs 1A). As the first spring (141) is both the penetration drive and injection drive (col 12, lns 14-16) injection head (142) is fully capable of meeting the appellant's plunger. The second spring (156) acts between injection head (142) and syringe (120) as it is physically located between the two elements as shown in Figs 1A-D. This interpretation of Bergens et al alone meets the appellant's claim recitations.

Alternatively, even if that interpretation has not convinced the Board, the rear end of the plunger (126) is shown proximal of spring (156) in Figs 1A-B and the spring (156) is between the rear end of the plunger and the syringe (120). Thus, since the physical location of spring (156) is between the rear end of the plunger (126) the syringe (120) the appellant's claim recitation has been meet.

Alternatively, even if both of those interpretations have not convinced the Board, Bergens et al still meets the appellant's claim recitation. To start, the Examiner notes "a second spring acting in compression between said plunger and the syringe" (clm 1, ln 14-15) can be interpreted in two ways. First, "a second spring acting in compression between said plunger and the syringe" (clm 1, ln 14-15) (emphasis added). Or, "a second spring acting in compression between said plunger and the syringe" (clm 1, ln 14-15) (emphasis added). Under the first interpretation, a simple physical location as discussed above meets the appellant's claims. Under the second interpretation, which the appellant seems to assert, a physical location would suffice but so would a functional relationship. As Merriam-Webster would define it, under the second interpretation the claim recitation would be "the doing of a thing"-"in common to" (act-

between) an "element A" (plunger) and an "element B" (syringe). In the present case, the second spring (156) acts in a load path against first spring (141). The first spring (141) acts driving the syringe from a protected position to a penetration position and then continues driving a dose from the syringe via the plunger. In opposition, second spring (156) exerts a contrary force dampening the force of the first spring on the plunger with respect to the syringe during the ejection of the dose. The second spring's exertion of a force in the load path in opposition to the first spring is plainly "the doing of a thing"-"in common to" the "plunger" and the "syringe."

3. There is no provision in Bergens et al teaching that the second spring delays the expulsion of the dose until the syringe has penetrated. Also, Bergens et al does not disclose that once the syringe reaches its forward position, the first spring compresses a second spring to urge the plunger forward to expel a dose, such that the syringe piston is not acted upon until the needle has penetrated. (Br. at 9, ¶ 4 & 10, ¶ 1).

The Examiner notes that as shown in Figs 1A and Figs 1B, when the syringe moves from its protected position (Figs 1A) to its penetrating position (Fig 1B) the piston (125) has not moved within the syringe. Furthermore, the legs (143) first act on plunger guide (153) shown in Fig 1A and then move inwardly to a narrow position shown in Figs 1B and finally Fig 1C to land on the rear end of syringe plunger 126 to exert force on 126 to drive fluid. The second spring (156) only exerts damper movement "after completed penetration" (col 10, lns 40-46; see ¶ 5 above). As discussed in col 12, lns 63-col 13, lns 8 (¶ 9 above), the end of the penetration movement the relative movement between parts has made the tapering surface (161) cause compression of legs (143) so the injection head has landed on the plunger (126) which continues forward movement with plunger guide (153) against the damping spring (156).

Furthermore, the Examiner notes that "the second spring delays the explusion of the dose until the syringe has penetrated" does not exactly match the appellant's claim recitations - namely, because that is not a present claim recitation. First, the appellant's recitation that "the second spring being in an expanded state when the syringe reaches its forward position" does not necessarily require that the second spring be in its most expanded state when reaching the forward position. Rather, if the spring is not completely compressed when reaching the forward position, then the spring is still in an expanded state from which the spring could be compressed more. Second, the recitation "said piston is not acted upon until the needle has penetrated" does not require that the "not acted upon" result be accomplished via a force from the second spring. Rather, if the piston is not acted upon until the needle has penetrated because the first spring (e.g. 141 of Bergens et al) must move the syringe into a penetrating position before the first spring engages the plunger which acts upon the piston, irrespective of a second spring, the claim recitation has met. Thus, since the appellant's claim scope differs from their purported arguments and because Bergens et al discloses that once the syringe reaches its forward position, the first spring compresses a second spring to urge the plunger forward to expel a dose, such that the syringe piston is not acted upon until the needle has penetrated, the Board is urged to affirm the rejection.

4. It would be non-sensical to interpose a spring acting between the syringe and the plunger in Bergens et al because pre-dribble is not an issue and the spring would counteract the force applied to the plunger (Br. at 6, ¶ 3 & 4)

The Examiner notes that the question of obviousness is not present because the claimed is anticipated by the reference under 35 USC § 102(b). The four ways to

overcome a 35 USC § 102(b) rejection are listed in MPEP 706.02(b) (See also MPEP 2133.02 & 2131.04). If Bergens et al discloses each and every element as set forth in the claim, then it anticipates the claim even if Bergens et al disparages or teaches away from the invention as the appellant appears to be alleging. MPEP 2131.05. As the question of whether a reference "teaches away" from the invention is inapplicable to an anticipation analysis and because Bergens et al discloses each of the appellant's claim elements as discussed above, the Board is urged to affirm the rejection.

5. . There is nothing in Bergens et al that would suggest the third, light spring (11) of the present invention so there is no proper rejection of claim 10 over the prior art (Br. at 10, ¶ 4)

The Examiner directs the Board to Fig 1A of Bergens et al showing a third, light spring (134) urging the syringe rearwardly so that its needle is retracted within the housing prior to use (Fig 1A). The appellant has failed to consider the Examiner's prima facie showing. Further, the appellant has failed to provide any substantive arguments rebutting such showing by presenting arguments distinguishing claim 10 over Bergens et al.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Andrew M Gilbert/

Examiner, Art Unit 3767

Conferees:

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767

/Janet C. Baxter/
TC 3700 TQAS